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APPLICATION NO. FILING DATE		ATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,909	05/26/20	000	BARRY N. GELLMAN	BSC-035CN	9128
21323	7590	02/28/2003			
•	RWITZ & TH	EXAM	EXAMINER		
HIGH STREE 125 HIGH ST	REET		HO, UYEN T		
BOSTON, M.	A 02110			ART UNIT	PAPER NUMBER
				3731	· <del>· · · · · ·</del>
				DATE MAILED: 02/28/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

Applicant(s)

	09/579,909	GELLMAN ET AL.					
Office Action Summary	Examin r	Art Unit					
	(Jackie) Tan-Uyen T. Ho	3731					
Th MAILING DATE of this communication app ars on the cov r sheet with the correspondence address eriod for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status	66(a). In no event, however, may a reply be tin within the statutory minimum of thirty (30) day fill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timel the mailing date of this c D (35 U.S.C. § 133).	y. ommunication.				
1) Responsive to communication(s) filed on 05 L	December 2002 .						
_	is action is non-final.						
3) Since this application is in condition for allowa closed in accordance with the practice under			ne merits is				
Disposition of Claims  4)⊠ Claim(s) 10-13,15 and 16 is/are pending in the	application						
,—							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>10-13,15 and 16</u> is/are rejected. 7)□ Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/or	r election requirement						
Application Papers	olookon roquirollicink						
9)⊠ The specification is objected to by the Examiner.							
10)⊠ The drawing(s) filed on <u>2/20/2003</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Ex	aminer.						
Priority under 35 U.S.C. §§ 119 and 120	•						
13) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a	n)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:							
<ol> <li>Certified copies of the priority documents</li> </ol>							
2. Certified copies of the priority documents	s have been received in Applicati	ion No					
<ul> <li>3. Copies of the certified copies of the prior application from the International But</li> <li>* See the attached detailed Office action for a list</li> </ul>	reau (PCT Rule 17.2(a)).		Stage				
14) Acknowledgment is made of a claim for domestic	c priority under 35 U.S.C. § 119(	e) (to a provisiona	l application).				
<ul> <li>a) ☐ The translation of the foreign language pro</li> <li>15) ☐ Acknowledgment is made of a claim for domesti</li> </ul>							
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	y (PTO-413) Paper No Patent Application (PT					

Application No.

#### **DETAILED ACTION**

1. The Request for Continued Examination and Amendment filed on 12/5/2002 are acknowledged. After careful reconsideration of this application, a new office action is made follow.

### **Drawings**

2. A copy of drawings was received on 2/20/2003. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: reference signs 9 (fig. 2) and 32, 38 (fig. 5). A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

#### Specification

3. The disclosure is objected to because of the following informalities: page 6, line 8, "edges 16" should be "edges 26". Appropriate correction is required.

## Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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5. Claims 10-12, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pietrzak et al. (5,527,342) in view of Sander et al. (5,522,817) and Anspach, III et al. (5,725,541).

Pietrzak et al. disclose a bone anchor (fig. 1) comprising: a cone-shaped head (14) having a wide end, a narrow end (figs. 1, 2), a pointed tip (24) at the narrow end; a collar member (20) being coupled and rotatable relative to the head (14) to secure the bone anchor in the bone (col. 4, lines 60-66 and col. 5, line 34 to col. 6, line 13); and a shaft (16) with an eyelet (18) for receiving a suture, wherein the shaft is coupled to the wide end of the head. Pietrzak et al. fails to disclose at least two cutting edges defined by one or more generally planar surfaces.

Anspach, III et al. disclose a bone anchor or bone fasteners (2) comprising a generally cone-shaped head (23) having three-side solid figure with triangular sides having sharp edges where the sides meet and wherein the edges are come together to from a pointed tip (figs. 6 and 9-12 and col. 5, lines 3-5, although, the figures does not show reference number 43 for the triangular sides and reference number 45 for the sharp edges as disclose in col. 5, lines 3-5, figures 6 and 9-12 do give enough illustration to show a cone shaped head (23) having flat surfaces come together to make sharp edges as disclose in col. 5, lines 3-5).

Sander et al. disclose a bone fastener or bone anchor (Figs. 1A, 1C, 2 and 3) including a generally cone shaped head (104, 201) having a narrow end, a wide end and two or more cutting edges (207) defined by generally planar surfaces (Figs. 1A, 1C,

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2 and 3), wherein the cutting edges come together to form a pointed tip at the narrow end for cutting through bone and hard tissue (col. 4, lines 19-41).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cone shape head of Pietrzak et al.'s bone anchor to have at least two or more cutting edges defined by planar surfaces wherein the cutting edges come together to form a pointed tip so that the sharp edges and pointed tip would cut into bone more easily.

Furthermore, (if for any reason that the applicants disagree with the examiner that the Sander et al. and Anspach, III et al. references teach cutting edges being defined by generally planar surfaces) it would haven been obvious matter of design choice to modify the bone anchor of Pietrzak et al. in view of Sander et al. and Anspach, III et al. by having the cutting edges defined by generally planar surfaces, since the applicant has not disclose that having the cutting edges defined by generally planar surfaces solves any stated problem or is for any particular purpose and it appears that the cutting edges of the bone anchor would perform equally well with either generally planar or non-planar surfaces that define the cutting edges.

6. Claims 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pietrzak et al. (5,527,342) in view of Sander et al. (5,522,817) and Anspach, III et al. (5,725,541) further in view of Thompson (5,697,931). The combination teaching of Pietrzak et al. in view of Sander et al. and Anspach, III et al. discloses all the limitations of the claim (see paragraph above) except fails to teach the bone anchor comprising titanium. Titanium is a well-known material in the art for example, Thompson teaches a

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bone anchor being made from titanium alloy (col. 13, lines 45-52). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the bone anchor of Pietrzak et al. in view of Sander et al. and Anspach, III et al. from titanium in order to provide sufficient strength for penetrating a bone.

#### Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Tinsley (5,636,846) disclose a device designed to adapt anchoring into a bone, wherein the device including a cone-shaped head having three sharp cutting edges come together to form a pointed tip and the cutting edges defined by at least two planar surfaces (fig. 13 and 17).

Smith (4,513,747) and Allen (5,403,344) disclose surgical devices including a cone shaped head having three sharp cutting edges come together to form a pointed tip and the cutting edges defined by at least two planar surfaces.

Stednitz et al. (5,098,435) disclose a device for penetrating into a bone including a cone shaped head having cutting edges which come together to form a pointed tip.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

(Jackie) Tan-Uyen T. Ho

Patent Examiner Art Unit 3731

February 22, 2003